


DATE: September 3, 2010

TO: Executive Board
Indiana State Department of Health

FROM: Dawn M. Adams 
Interim Assistant Commissioner
Health and Human Services Commission

SUBJECT: Preliminary Adoption of Amendments to 410 IAC 3-3
Newborn Screening Rule

The Indiana State Department of Health (ISDH) requests the Executive Board, at the Board's September 8, 2010, meeting, to preliminarily adopt these proposed amendments to the Newborn Screening Rule (410 IAC 3-3).

The proposed rule amendments would update the current rule to add the Early Hearing Detection and Intervention Program (EHDI) and reflect Newborn Screening and EHDI's current operations. 410 IAC 3-3 has not been updated since 1986 (the rule was readopted twice in 2001 and 2007, respectively).

The proposed rule amendments would do the following:

- add screening requirements, responsibilities, and protocols for the Early Hearing Detection and Intervention Program, including appropriate follow-up
- add definitions pertaining to the Early Hearing Detection and Intervention Program and add other necessary definitions
- clarify rules related to fees for newborn screening
- update the list of conditions for which newborns shall receive screening and for which reporting is required:
 - specify sickle cell anemia
 - add cystic fibrosis
 - add hearing impairments
 - add "other genetic conditions"
- clarify responsibilities for provision of program equipment and supplies and add information on the program's provision of metabolic formula
- update procedures for follow up of positive screenings
- update requirements designated laboratories must meet to perform screening tests
- update required laboratory reporting
- update requirements for hospitals, birthing centers, midwives, and physicians providing home birth services to maintain a screening log, report to ISDH, and perform follow up

- update the follow up of positive results by responsible physicians and the related ISDH recommendations

A Notice of Intent to Adopt a Rule was posted on the Indiana Register website on August 11, 2010, starting the one-year period in which to adopt this rule amendment. The proposed rule amendment is attached.

Attachment: Proposed Rule